DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097

September 24, 2002

WARNING LETTER
CIN-02WL-14903

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Francis L. Bäby, President
HomeReach, Inc.
404 East Wilson Bridge Rd.
Worthington, OH 43085

Dear Mrs. Bäby:

The Food and Drug Administration conducted an inspection of your medical gas facility, HomeReach, Inc., at 7708 Green Meadows Dr., Suite D, Lewis Center, OH, on August 27-28, 2002. This inspection covered your transfilling of Oxygen USP liquid. Oxygen USP is a drug as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Our inspection found significant deviations from the current Good Manufacturing Practices for drug products set forth in Title 21, Code of Federal Regulations, (21 CFR) Parts 210 and 211 . These deviations cause your medical gases to be adulterated within the meaning of sections 501(a)(2)(B) and 501(b) of the Federal Food, Drug and Cosmetic Act (the *Act*).

Specific observations made during the Inspection include:

1) Failure to reject drug products which fail to meet established standards and specifications (21 CFR 211.165(f)). Your firm has released and shipped liquid Oxygen USP, which assayed below the USP purity limit of 99.0%, at least [redacted] ([redacted] times between 12-28-01 and 3-7-02. (Specifically: Oxygen USP tested 98.9% purity, on12/28/01; 97.9-98.5% on 2/26&27/02; and 98.7% on 3/5,6&7/02.) Drug products that are recognized in an official compendium (i.e., USP), and whose strength differs from, or whose quality or purity fall below the standards set forth in such compendium are adulterated under section 501(b) of the *Act*.

2) Failure to calibrate analytical instruments at suitable intervals (21 CFR 211.160(b)(4)). Specifically: Your firm has filled liquid Oxygen USP into vehicle mounted vessels on at least [redacted] dates between 9-14-01 and 7-29-02 without calibrating the oxygen analyzer span each day of use, as required by the analyzer's instruction manual.

3) Failure to document review and approval of all drug product production and control records by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed (21 CFR 211.192). Batch production records were not signed by a second person as approved for distribution on at least [redacted] fill records dating from 8-31-01 to 6-14-02. Records of bulk tank fills failed to show the necessary approval for the following dates: 8-31-01; 12-19-01; 3-7-02; 3-23-02; 4-16-02; 4-21-02; 5-2-02; 5-10-02; 5-26-02; 5-28-02; 6-2-02; and 6-14-02. Each of these records typically covers fills extending over a one or two week period.

4) Failure to establish and follow appropriate written procedures for production and process control (21 CFR 211.100). Your firm has no written operating procedures for filling out the delivery vessel fill log and ID tags or for conducting review of batch production records (delivery vessel fill logs).

In addition, our investigators made the following observations which were not included on the form FDA-483, Inspectional Observations, nor discussed with you at the conclusion of the inspection:

- Oxygen analyzer calibration records for 3/7/02 were either calibrated incorrectly or the results improperly entered. The zero on the analyzer is supposed to be set at "0" using a certified nitrogen standard. The 3/7/02 calibration records show the zero calibration set at 99.9% using a nitrogen standard cylinder (21 CFR 211.160(b)(4)).

- Three (3) vehicle mounted vessel fill records had no documentation of analysis. These were batch records with bulk delivery dates of 10/1/01, 12/19/01 and 8/12/02 (21 CFR 211.165(a)).

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against award of contracts for affected products.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations.

Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of Charles S. Price, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,

John W. Thorsky
Acting District Director
Cincinnati District

Cc: Pamela J. Ellis
Director HME Services
HomeReach, Inc.
7708 Green Meadows Dr., Suite D
Lewis Center, OH 43035